JS 44 (Rev. 08/18)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

United States of America

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Deidre L. Colson, AUSA U.S. Attorney's Office
63 South Royal Street, Suite 600 Mobile, AL 36602 251-415-7192

DEFENDANTS

Heritage Compounding Pharmacy, LLC, Christopher A. Burgess & Marti P. Burgess

County of Residence of First Listed Defendant Baldwin
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

Brad Howard, Esq. of Brown & Fortunato, P.C.
S. Fillmore, Suite 400 in Amarillo, Texas 79105

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☒ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☒ 4	☒ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

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- ☐ 195 Contract Product Liability
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- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
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- ☐ 371 Truth in Lending
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- ☐ 862 Black Lung (923)
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V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
31 U.S.C. §§ 3729-3733

Brief description of cause:
False or fraudulent claims to federal health care programs

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):
JUDGE _____ DOCKET NUMBER _____

DATE 10/29/19

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
vs.	)	**CIVIL ACTION NO.:19-870**
	)	
HERITAGE COMPOUNDING PHARMACY, LLC, CHRISTOPHER A. BURGESS AND MARTI P. BURGESS	)	
	)	
Defendants.	)	

COMPLAINT

The United States of America, on behalf of the United States Department of Defense , brings this action against Defendants, Heritage Compounding Pharmacy, LLC ("Heritage"), Christopher A. Burgess), and Marti P. Burgess, under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, and the common law, to recover treble damages sustained by, and civil penalties and restitution owed to, the United States. As set forth more fully below, from January 1, 2013 to May 1, 2015 (the "relevant time-period"), Defendants knowingly submitted, and/or caused the submission of, claims for reimbursement to TRICARE that were tainted by illegal kickbacks in the form of extravagant perks, dinners, and entertainment to induce physician prescribing of Heritage's pre-formulated compounded creams. In addition, Defendants implemented a marketing and refill scheme targeting TRICARE beneficiaries that generated false claims for prescriptions that were prepared by Heritage, were not medically necessary, and/or were not prescribed by a physician who had a legitimate physician-patient relationship.

I. PARTIES

1. Plaintiff the United States of America ("United States") brings this action on behalf of the

Department of Defense ("DOD"), and DOD component the Defense Health Agency ("DHA"), which administers the TRICARE program.

2. Defendant Heritage Compounding Pharmacy, LLC ("Heritage") is a limited liability company formed in the State of Alabama on February 3, 2006, with its principal place of business in Mobile, Alabama. Heritage is an independently owned compounding pharmacy that received over $5.3 million in reimbursements from TRICARE for compounding drug claims from January 1, 2013 to May 1, 2015.

3. Defendant Christopher A. Burgess ("Burgess") is a resident of the State of Alabama and resides at 322 N. Ingleside Street, Fairhope, Alabama 36532. Burgess is a licensed and registered pharmacist and owner/operator of Heritage during all relevant times of this Complaint.

4. Defendant Marti P. Burgess ("M. Burgess") is a resident of the State of Alabama and resides at 322 N. Ingleside Street, Fairhope, Alabama 36532. Marti Burgess is a licensed and registered pharmacist who conducted management and oversight functions of Heritage during the relevant time period, and became a 20% owner of Heritage in November 2015.

II. JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and § 1345 because this action is brought by the United States as a Plaintiff pursuant to the FCA.

6. This Court may exercise personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) and because Defendants reside or transact business in the Southern District of Alabama.

7. Venue is proper in the Southern District of Alabama under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Defendants reside or transact business in this District and the violations of the FCA described herein were carried out in this District.

III. GOVERNING LAWS AND REGULATIONS

A. THE FALSE CLAIMS ACT

8. The FCA imposes liability upon any person who "knowingly presents, or causes to be presented [to the government] a false or fraudulent claim for payment or approval;" or "knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim". 31 U.S.C. §§ 3729(a)(1)(A) and (B). The FCA also imposes liability for knowingly concealing or improperly avoiding or decreasing an obligation to the United States. *Id*. (a)(1)(G).

9. The FCA's scienter requirement is satisfied by either actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information submitted. 31 U.S.C. § 3729(b) (1). The statute further clarifies that "no proof of specific intent to defraud is required." *Id.*

10. The knowing request of federal reimbursement for the provision of medical services that fail to meet the criteria set forth in federal statutes and regulations constitutes a violation of the FCA.

B. THE ANTI-KICKBACK STATUTE

11. The Anti-Kickback Statute ("AKS") arose out of congressional concern that inducements may corrupt patient and professional health care decision-making, impose higher costs on federal health care programs, and divert federal funds towards goods and services that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population.

12. The AKS makes it illegal for an individual or entity to knowingly and willfully:

> [O]ffer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be

> made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(2).

13. A claim for reimbursement from a federal health care program for items or services resulting from a violation of the AKS "constitutes a false or fraudulent claim" under the FCA. 42 U.S.C. § 1320a-7b(g). Under this provision, claims submitted to federal health care programs that result from violations of the AKS are per se false or fraudulent within the meaning of 31 U.S.C. § 3729(a)(1)(A)-(B). Accordingly, a person violates the FCA when he or she knowingly submits or causes to be submitted claims to federal health care programs that result from violations of the AKS.

14. Specific intent is not required to establish a violation of the AKS. *See* 42 U.S.C. § 1320a-7b(h). A person need not have actual knowledge of this section or specific intent to commit a violation of this section.

C. THE TRICARE PROGRAM

15. TRICARE (formerly known as CHAMPUS) is a federal health care program that is administered by DHA, a component of DOD. TRICARE provides health care insurance for active duty military personnel, military retirees, and military dependents.

16. TRICARE contracts with Express Scripts, Incorporated ("ESI") to administer the prescription drug coverage of the TRICARE program, including the processing and payment of claims for reimbursement from TRICARE for compounded prescription drugs.

17. At all relevant times, TRICARE covered compounded drugs that are medically necessary and proven to be safe and effective. 32 C.F.R. § 199.4 (g)(15).

18. Compounding is the practice in which a licensed pharmacist or physician combines, mixes, or alters the ingredients of a drug to create a medication tailored to the needs of an individual patient.

19. During the relevant time period, TRICARE reimbursed pharmacies on a per compound ingredient basis.

20. Effective May 1, 2015, TRICARE changed its compounded drug reimbursement policy and required electronic screening of each ingredient to ensure the following: 1) TRICARE covers the ingredient, 2) the ingredient is safe and effective, and 3) it is medically necessary. TRICARE also requires medical necessity pre-authorization for certain compounded drugs.

21. At all relevant times, TRICARE beneficiaries were responsible for sharing the costs of compounded drug prescriptions filled by a retail or mail-order pharmacy by paying a copayment. 10 U.S.C. § 1074g(a)(6); TRICARE Reimbursement Manual, Chapter 2, Addendum B.

22. A pharmacy seeking reimbursement from TRICARE must comply with TRICARE's anti-fraud and abuse provisions. 32 C.F.R. § 199.9(a)(4). Fraudulent situations include commission and kickback arrangements. *Id.* § 199.9(c)(12). Abusive situations include the routine waiver of patient copayments. *Id.* § 199.9(b)(1).

23. Fraud or abuse by a pharmacy may result in the denial of the pharmacy's claims or the exclusion or suspension of the pharmacy from participation in the TRICARE program. 32 C.F.R. § 199.9(b), (f).

24. TRICARE regulations specify that "[a]ll fraud, abuse, and conflict of interest requirements [in section 199.9] are applicable to the TRICARE pharmacy benefits program." 32 C.F.R. § 199.21(p). TRICARE's contract with ESI also incorporates the provisions of 32 C.F.R. § 199.

25. To receive reimbursement from TRICARE for compounded drugs, a pharmacy must enter

into a Provider Agreement with ESI. A Provider Agreement is essential to TRICARE claims submission.

26. During the relevant time period, Burgess and Heritage were authorized to receive reimbursement from TRICARE for compounded drugs pursuant to an executed provider authorization and/or a pharmacy provider service agreement with ESI.

IV. FACTS

A. TARGETED RE-FILLS AND NO LEGITIMATE PHYSICIAN-PATIENT RELATIONSHIP

27. Compound medications are specially formulated, personalized medications prepared by licensed pharmacists for individual patients for whom commercially manufactured medications are unavailable or unsuitable.

28. Compounding differs from the prescription of standardized, manufactured drugs, in that it involves a relatively more intimate, interactive practitioner-patient-pharmacist relationship; a customized, patient-specific physician prescription order; and the preparation of a relatively small quantity and generally commercially unavailable medication for a specific patient, as opposed to pre-made preparations for non-specific patients.

29. Effective January 1, 2012, TRICARE began paying for each individual ingredient in a compound medication, including bulk chemicals, rather than limiting payment to the most expensive active ingredient in the compounded medication. This change in reimbursement made compounded prescriptions more lucrative.

30. Beginning in 2012, Burgess expanded his compounding pharmacy business, entering into a license servicing agreement and maintaining a membership in a compounding specialty pharmacy group for a fee of $25,000.00 per year. Burgess learned about marketing compounded products and how to maximize profits through a sales force, received updates on

DHA/TRICARE's reimbursement policies, and had access to numerous pre-formulated patented topical pain cream formulas.

31. In 2012, Heritage and Burgess began hiring marketing representatives to promote topical pain creams to prescribing physicians in specified territories with a high population of TRICARE beneficiaries. Heritage territories included "Southwest Missouri," "Topeka/Manhattan," and "Kansas City" all of which were near military institutions and facilities.

32. In addition to base pay, Heritage marketing representatives were compensated with an additional 10% commission on compounded medications prepared from bulk chemicals.

33. Heritage provided its marketing representatives with pre-printed, check-the-box prescription pads that contained a list of 4 to 5 pre-formulated topical pain creams, and two pre-formulated dosage regimens. *See Compounded Treatments – Topical Pain Management Prescription* attached hereto, and incorporated herein, as Exhibit "1".

34. Burgess directed the marketing representatives to provide pre-printed Heritage prescriptions to physicians to use in prescribing. Heritage pharmacy staff routinely completed the forms for the prescriber.

35. Once the marketing representative secured a pre-printed Heritage prescription through the prescribing physician's office, Heritage pharmacists and/or staff conducted a call/contact regimen with the TRICARE beneficiary pursuant to its policies and procedures -- "*Pain Cream Prescription Standard Operating Procedures*" and "*Topical Pain Management – Targeted Refill Phone Calls.*"

36. The Heritage targeted refill protocol essentially consisted of an initial consult, a 2-week consult, and refill consults every 30-45 days in an effort to maximize TRICARE beneficiary refills and to encourage the patient to continue and increase usage. Heritage continued with "follow-up"

calls every 30-45 days even if the patient indicated they did not want a refill and/or if they did not respond well to the medication.

37. As a result of Heritage's targeted refill policy, many TRICARE beneficiaries automatically received refills of compounded pain creams from Heritage that they did not want or need.

38. Sometime in 2013, Heritage expanded its targeted phone call protocol and established a "Call Center" run by its pharmacists for the sole purpose of generating new higher reimbursement high dose regimen ("HDR") prescriptions and refills without regard to a patient's medical needs. Thirty day HDR prescriptions generally increased reimbursements by $4,000.00 to $6,000.00, and 90-day HDR prescriptions increased reimbursements by about $22,000.00.

39. From January 1, 2013 to May 1, 2015, Heritage billed TRICARE $6,369,359.53 for these pre-formulated topical pain creams.

40. The pre-formulated compounded prescriptions used by Heritage were not individualized for a particular patient and were not prescribed by a physician and/or by a physician in collaboration with a pharmacist.

B. MARCH 2014 HIGH DOSE REGIMEN (HDR) 90-DAY REFILL SCHEME

41. On January 9, 2014, and again on March 4, 2014, Burgess, M. Burgess and Heritage, received information about TRICARE's upcoming implementation of enhanced compound screening processes effective April 1, 2014.

42. In response, Burgess directed Heritage pharmacists to refill as many TRICARE prescriptions as they could prior to the April 1, 2014 reimbursement change.

43. Defendants created a target list of TRICARE beneficiaries who held active 30-day prescriptions for topical pain creams and provided the target list to the respective marketing representatives according to their territory and prescribing physician. Heritage marketers requested

new HDR 90-day prescriptions from the prescribing physician for the TRICARE beneficiaries identified on the target list.

44. While the marketers were having success at obtaining stand-by scripts, Heritage staff contacted the targeted TRICARE beneficiaries to persuade them of their need for a HDR 90-day prescription as opposed to their existing 30-day refill prescription. This marketing push focused on the high reimbursement pre-formulated topical pain cream that contained Ketamine, a Schedule III controlled substance ("Ketamine Formula").

45. If the patient acquiesced or did not affirmatively object to the prescription pushed by Heritage, Heritage marketers or other pharmacy personnel contacted the prescribing doctor's office, typically speaking to a staff member, to secure the stand-by HDR 90-day prescription of the Ketamine Formula.

46. During this targeted refill process, neither the physician nor the physician's staff personnel, communicated with the patient about his or her medical condition or the medical need for such medication.

47. According to medical records reviewed, most of these TRICARE beneficiaries did not have a corresponding office visit, office note, or telephone note that documented the medical need for a new HDR 90-day pain cream prescription that included the controlled substance Ketamine.

48. The new HDR 90-day Ketamine Formula prescription equated to 2,700 grams of medication (the equivalent of 6 pounds), which could not possibly be used during the time period prescribed or prior to the medication expiring. TRICARE reimbursed Burgess, M. Burgess and Heritage in the amount of $27,000.00 + per claim.

49. For March 2014 alone, TRICARE's reimbursements to Heritage totaled $955,196.00 just for the HDR 90-day Ketamine Formula.

C. MARCH 2014 HDR 90-DAY REPRESENTATIVE CLAIMS

50. On December 13, 2013, a neurologist located in Manhattan, Kansas, identified, in order of priority, three choices on Heritage's pre-formulated topical pain cream prescription pad for TRICARE Beneficiary "A." *See redacted prescription* attached hereto, and incorporated herein as Exhibit "2." The 30 day quantity dispensed included a pre-printed dosage of "up to four grams three to four times daily for treatment of pain and/or muscles spasm," and five refills. *Id*.

51. On December 16, 2013, Heritage filled the physician's second choice, a 30-day prescription (480 grams) of Formula No. 5 with Ketamine, for TRICARE Beneficiary "A." TRICARE reimbursed Heritage in the amount of $5,043.41.

52. Although TRICARE Beneficiary "A" had an existing prescription with 5 refills, and none of the refills had been used, on March 13, 2014, Heritage contacted the patient to persuade TRICARE Beneficiary "A" to authorize a new HDR 90-day prescription (2,700 grams).

53. On March 19, 2014, Heritage contacted the physician's office staff to secure a verbal order for TRICARE Beneficiary "A." Heritage staff completed the verbal order checking Formula No. 3 with Ketamine, the HDR dosage (2700 grams), and a 90-day dispense quantity with no refills. *See* Exhibit 2, p.2. TRICARE Beneficiary "A" did not communicate with the physician's office regarding this new prescription.

54. Heritage billed the claim to TRICARE, receiving reimbursement in the amount of $27,171.58.

55. The representative claims data for TRICARE Beneficiary "A" are as follows:

TRICARE BENE	FILL_DT	PAID_AMT	QTY	DAYS	DRUG	ING6_DRG
A	12/16/13	$5,043.41	480.00	30	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
A	03/19/14	$27,171.58	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
		$32,214.99				

56. Similarly, on January 24, 2014, using Heritage pre-printed prescriptions forms, the same physician prescribed any one of the following topical pain creams by priority for TRICARE Beneficiary "B:" (1) Formula No. 7 (Lidocaine, Prilocaine, Lamotrigine, Meloxicam); (2) Formula No. 5 (Nabumetone, Amitriptyline, Gabapentin, Lidocaine, Prilocaine, Ketamine, Magnesium); or (3) Formula No. 4 (Gabapentin, Lidocaine, Prilocaine). The pre-printed prescription identified a 30-day quantity of the low dose regimen (480 grams) with five refills. *See TRICARE Beneficiary "B" prescription* attached hereto, and incorporated herein as Exhibit "3."

57. On January 27, 2014, Heritage filled Formula No. 5 with Ketamine (Choice No. 2), and TRICARE paid Heritage $5,243.85.

58. Although the patient had an existing prescription with five refills, and none of the refills had been used, on March 19, 2014, Heritage contacted TRICARE Beneficiary "B" to persuade the beneficiary to authorize a new HDR 90-day script (2700g) of the topical pain cream containing Ketamine.

59. On March 19, 2014, Heritage contacted the physician's office staff to secure a verbal order for TRICARE Beneficiary "B." Heritage staff completed the verbal order checking Formula No. 3 with Ketamine, the HDR dosage (2700 grams), and a 90 day dispense quantity with no refills. *See* Exhibit 3, p.2.

60. Heritage billed TRICARE and received reimbursement in the amount of $27,171.58.

61. The representative claims data for TRICARE Beneficiary "B" are as follows:

TRICARE BENE	FILL_DT	PAID_AMT	QTY	DAYS	DRUG	ING6_DRG
B	01/27/14	$5,243.85	480.00	30	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
B	03/19/14	$27,171.58	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
		$32,415.43				

62. Heritage completed this new HDR 90-day prescription process for the physician's existing TRICARE beneficiaries who held topical pain cream prescriptions. The Heritage March 2014 refill

scheme for just one physician totaled $488,606.32 and is reflected in the following TRICARE claims data chart:

TRICARE BENE	FILL_DT	PAID_AMT	QTY	DAYS	DRUG	ING6_DRG
A	03/19/14	$27,171.58	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
B	03/19/14	$27,171.58	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
C	03/07/14	$27,120.15	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
D	03/07/14	$27,120.15	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
E	03/19/14	$27,120.58	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
F	03/19/14	$27,120.58	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
G	03/07/14	$27,120.15	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
H	03/18/14	$27,120.15	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
I	03/18/14	$27,171.15	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
J	03/19/14	$27,120.58	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
K	03/18/14	$27,171.15	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
L	03/10/14	$27,171.15	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
M	03/24/14	$27,100.85	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
N	03/18/14	$27,120.15	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
O	03/18/14	$27,120.15	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
P	03/07/14	$27,171.15	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
Q	03/05/14	$5,126.24	480	30	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
R	03/18/14	$22,097.68	2,700.00	90	FLURBIPROFEN POWDER	PCCA CUSTOM LIPO-MAX
S	03/07/14	$27,171.15	2,700.00	90	NABUMETONE MICRONIZED POWDER	KETAMINE HCL POWDER
		$488,606.32				

D. 2014 ESI PROGRAM INTEGRITY AUDIT

63. In April 2014, and in response to a TRICARE beneficiary complaint regarding medication costing $28,000.00 that he did not want or need, ESI Program Integrity (ESI PI) conducted a desk audit of, among other things, pre-printed prescriptions with medications containing Ketamine that did not appear to be prepared by the prescriber or their designated agents per controlled substance requirements.

64. On behalf of Heritage, M. Burgess oversaw the ESI desk audit and the subsequent recoupment by TRICARE of overpayments identified in the audit.

65. Despite the ESI PI findings and recoupment of funds from Heritage, neither Burgess nor M. Burgess conducted a comprehensive, proactive review of other potential TRICARE overpayments that were due to be returned. With actual knowledge that the pre-printed Ketamine

prescriptions and 90-day refills were invalid, Heritage retained TRICARE reimbursement for similar pre-printed prescriptions and claims.

66. With actual knowledge of their invalidity, Heritage continued to seek reimbursement using pre-printed compounding forms until TRICARE changed its compounded drug reimbursement policy in May 2015.

67. Burgess and Heritage began terminating marketing representatives in 2015 after TRICARE changed its reimbursement policy for compounded medications.

E. HERITAGE KICKBACK SCHEME

68. Heritage marketing representatives often encouraged providers to prescribe Heritage compounds by providing kickbacks in the form of office lunches, dinners, gift cards, sporting events, and other extravagant perks and entertainment.

69. In 2014, a Heritage marketing representative located in the Kansas City, Missouri area, purchased and Heritage reimbursed, Paul McCartney concert tickets in the amount of $1,121.00 for a prescribing physician.

70. Additional Heritage reimbursed kickbacks to prescribing physicians included: Major League Baseball tickets in the amount of $2,460.00, NBA tickets in the amount of $637.00, Tony Bennett concert tickets in the amount of $784.00, and John Legend concert tickets in the amount of $812.95.

71. As a condition of payment by TRICARE, a pharmacy must comply with the AKS and must not offer or pay anything of value to third parties in exchange for referring, arranging or recommending TRICARE patients for prescriptions to be filled by the pharmacy reimbursed by TRICARE.

72. Pursuant to the Provider Agreements with ESI, Heritage and Burgess certified compliance

with all applicable fraud, waste and abuse laws, which include the AKS and the FCA.

73. Defendants knew that compliance with the AKS was a material requirement for receiving TRICARE reimbursement.

F. THE UNITED STATES SUFFERED DAMAGES.

74. From January 1, 2013 through May 1, 2015, TRICARE paid approximately 5.3 million dollars to Heritage for these pre-formulated topical pain creams.

75. During the relevant time period, Heritage claims were illegally induced by kickbacks paid to providers.

76. During the relevant time period, Defendants sought reimbursement from TRICARE for compounding prescription claims that were not prescribed pursuant to a valid physician-patient relationship, that were not individualized and prescribed by a physician, and that were not medically necessary.

COUNT ONE
(False or Fraudulent Claims)
(False Claims Act, 31 U.S.C. § 3729(a)(1)(A))

77. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 76.

78. By virtue of the acts described above, Defendants knowingly presented or caused to be presented to the United States false or fraudulent claims for payment or approval, in violation of the FCA, 31 U.S.C. § 3729(a)(1)(A).

79. Defendants knowingly submitted false claims for reimbursement that did not arise from a valid patient-prescriber relationship, were not medically necessary, or were induced by kickbacks.

80. By reason of the foregoing, the United States suffered actual damages in an amount to be determined at trial, and therefore is entitled under the FCA to treble damages plus a civil penalty

for each false or fraudulent claim.

COUNT TWO
(False Records or Statements Material to False Claims)
(False Claims Act, 31 U.S.C. § 3729(a)(1)(B))

81. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 80.

82. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims that were paid and approved by the TRICARE program, in violation of the FCA, 31 U.S.C. § 3729(a)(1)(B).

83. Defendants agreed as an Authorized Provider with ESI to comply with the AKS, FCA, and applicable state law.

84. The false representations of compliance were material to TRICARE's payment of the false claims.

85. Said false records and statements were made, used, or caused to be made or used, with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

COUNT THREE
(Reverse False Claims - False Claims Act. 31 U.S.C. § 3729(a)(l)(G))

86. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 85.

87. By and through the fraudulent schemes described herein, Defendants knowingly concealed or knowingly and improperly avoided an obligation to pay or transmit money or property to the United States. With the 2014 ESI audit, Defendants had actual knowledge that the pre-printed compounding pain formulas that included Ketamine were invalid. Yet, Defendants took no action to satisfy their obligations to the United States to repay or refund those payments and instead

retained the funds and continued to bill the United States.

88. As a result of Defendants' fraudulent conduct, the United States has suffered damage in the amount of funds that belong to the United States but are improperly retained by Defendants.

COUNT FOUR
(Payment by Mistake)

89. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 88.

90. This is a claim under federal common law by the United States for the recovery of monies that TRICARE paid to Heritage by mistake for compounded drugs that were tainted since prescribed drug did not arise from a valid patient-prescriber relationship or was induced by kickbacks to providers from Heritage marketers.

91. As a consequence of the conduct and the acts set forth above, the United States mistakenly paid Heritage an amount to be determined which, under the circumstances, in equity and good conscience, should be returned to the United States.

COUNT FIVE
(Unjust Enrichment)

92. The United States re-alleges and incorporates by reference the allegations of paragraphs 1 through 91.

93. This is a claim under federal common law by the United States for recovery of monies by which Heritage has been unjustly enriched.

94. By virtue of the conduct and the acts described above, Heritage was unjustly enriched at the expense of the United States in an amount to be determined, which, under the circumstances, in equity and good conscience, should be returned to the United States.

PRAYER FOR RELIEF AND JURY DEMAND

WHEREFORE, the United States respectfully prays for judgment in its favor as follows:

a. As to the First, Second and Third Causes of Action (False Claims Act), against Defendants for: (i) statutory damages in an amount to be established at trial, trebled as required by law, and such penalties as are required by law; (ii) the costs of this action, plus interest, as provided by law; and (iii) any other relief that this Court deems appropriate, to be determined at a trial by jury.

b. As to the Fourth Cause of Action (Payment Under Mistake of Fact), for: (i) an amount equal to the money paid by the United States through the TRICARE Program to Heritage, and illegally retained by Heritage, plus interest; (ii) the costs of this action, plus interest, as provided by law; and (iii) any other relief that this Court deems appropriate, to be determined at a trial by jury.

c. As to the Fifth Cause of Action (Unjust Enrichment), for: (i) an amount equal to the money paid by the United States through the TRICARE Program to Heritage, or the amount by which Heritage was unjustly enriched, plus interest; (ii) the costs of this action, plus interest, as provided by law; and (iii) any other relief that this Court deems appropriate, to be determined at a trial by jury.

d. All other and further relief as the Court may deem just and proper.

e. The United States hereby demands a jury trial on all claims alleged herein.

Respectfully submitted,

RICHARD W. MOORE
UNITED STATES ATTORNEY

By: */s/ Deidre L. Colson*

DEIDRE L. COLSON
Assistant United States Attorney
U.S. Attorney's Office
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Mobile, AL 36602
(251) 415-7105
deidre.colson@usdoj.gov

Heritage
COMPOUNDING PHARMACY
[redacted]
Mobile, Alabama 36608
t. 877.703.0004
f. 877.871.7142
heritagecompound.com

COMPOUNDED TREATMENTS FOR TOPICAL PAIN MANAGEMENT

Patient's Name: Date:

Patient's Date of Birth: Patient's Phone Number:

Patient's Address: State: Zip:

Allergies:

PLEASE FAX COPIES OF BOTH MEDICAL AND PRESCRIPTION CARDS

Physician's Name: Signature:

Phone Number:

I have indicated by number(s) below, in order of preference, the medication(s) I am prescribing. The pharmacy shall dispense my first preference, unless not covered by the patient's insurance, in which case the pharmacy shall proceed in similar manner based on my order of preference. The pharmacy may dispense any drug selected below, regardless of order of preference, based on the patient's choice.

Prescribed Medications: (CMPD indicates a medication that has been compounded by the pharmacy)

1. ____ CMPD Flurbiprofen 10%, Cyclobenzaprine 1%, Gabapentin 6%, Lidocaine 2%, Prilocaine 2% in LAM*
2. ____ CMPD Flurbiprofen 10%, Amitriptyline 1%, Gabapentin 6%, Lidocaine 2%, Prilocaine 2% in LAM*
3. ____ CMPD Gabapentin 10%, Lidocaine 2%, Prilocaine 2% in LAM*
4. ____ CMPD Nabumetone 15%, Amitriptyline 2%, Gabapentin 6%, Lidocaine 2%, Prilocaine 2%, Ketamine 5%, Magnesium 5% in LAM*
5. _____ Other:

6. ____ CMPD Lidocaine 2%, Prilocaine 2%, Lamotrigine 2.5%, Meloxicam 0.09% Topical Cream

Directions: (Directions selected below apply to all medications indicated above – PLEASE CHECK DESIRED DOSING)

____ Apply up to four grams three to four times daily for treatment of pain and / or muscle spasms

____ High Dosing Regimen - Apply sufficient quantity to painful areas up to five times daily – maximum usage per day (in quantity) is 30 grams (6 grams per treatment)

____ Other:

Quantity to Dispense: _____ days (30 day supply unless otherwise indicated here)

If checked below, please dispense the following as an accompanying prescription to the above prescribed therapy

Refills: (Refills expire after one year if not utilized)

0 1 2 3 4 5 1 Year

Three commercially available medications (1) Lidocaine2.5%/Prilocaine 2.5% Cream, (2) Lamotrigine 200mg Tablets, and (3) Meloxicam 15mg Tablets are being compounded together in a proprietary patent-pending process that results in the concentrations listed above in #6 which is CMPD Lidocaine 2%, Prilocaine 2%, Lamotrigine 2.5%, Meloxicam 0.09% Topical Cream. LAM® stands for Lipoderm Active-Max™ which is a trademark of PCCA. Spira-Wash-Gel™ is a water-miscible base and also a trademark of PCCA. Lidocaine 2% listed above equals Lidocaine HCl 2.46%. Prilocaine 2% listed above equals Prilocaine HCl 2.33%. Flurbiprofen, Nabumetone, and Gabapentin percentages listed above are based upon USP versions of the drug. Amitriptyline, Cyclobenzaprine, and Ketamine percentages listed above are based upon HCl versions of the drug. Magnesium percentage listed above is based upon a Sulfate version of the drug. As always, the FDA does not review any compounded medication for safety or efficacy.

EXHIBIT 1

Heritage
COMPOUNDING PHARMACY

t: 1.877.703.0004
f: 1.877.871.7142
heritagecompound.com

COMPOUNDED TREATMENTS FOR TOPICAL PAIN MANAGEMENT

Patient's Name: [redacted] Date: 12-13-13

Patient's Date of Birth: [redacted] Patient's Phone Number: [redacted]

Patient's Address: [redacted] State: [redacted] Zip: [redacted]

Allergies: Last Four of SSN: [redacted]

PLEASE FAX COPIES OF BOTH MEDICAL AND PRESCRIPTION CARDS

Physician's Name: Dr Nanda Kumar Signature: [signature]

Phone Number: [redacted]

I have indicated by number(s) below, in order of preference, the medication(s) I am prescribing. The pharmacy shall dispense my first preference, unless not covered by the patient's insurance, in which case the pharmacy shall proceed in similar manner based on my order of preference. The pharmacy may dispense any drug selected below, regardless of order of preference, based on the patient's choice.

Prescribed Medications: *(CMPD indicates a medication that has been compounded by the pharmacy)*

1. ___ CMPD Flurbiprofen 10%, Cyclobenzaprine 1%, Gabapentin 6%, Lidocaine 2%, Prilocaine 2% in LAM*
2. ___ CMPD Flurbiprofen 10%, Amitriptyline 1%, Gabapentin 6%, Lidocaine 2%, Prilocaine 2% in LAM*
3. ___ Circulation: Nifedipine/Pentoxifylline/Ketamine/Gabapentin/Lidocaine/Prilocaine 10%/5%/10%/6%/3%/3%. Apply up to 4 grams three times a day, apply heat before and after. Wipe off excess.
4. (3) CMPD Gabapentin 10%, Lidocaine 2%, Prilocaine 2% in LAM*
5. (2) CMPD Nabumetone 15%, Amitriptyline 2%, Gabapentin 6%, Lidocaine 2%, Prilocaine 2%, Ketamine 5%, Magnesium 5% in LAM*
6. ___ Other:
7. (1) CMPD Lidocaine 2%, Prilocaine 2%, Lamotrigine 2.5%, Meloxicam 0.09% Topical Cream

Directions:
Apply up to four grams three to four times daily for treatment of pain and / or muscle spasms

Quantity to Dispense: 30 **days** *(30 day supply unless otherwise indicated here)*

If checked below, please dispense the following as an accompanying prescription to the above prescribed therapy

Refills: *(Refills expire after one year if not utilized)*

0 1 2 3 4 (5) 1 Year

Three commercially available medications (1) Lidocaine2.5%/Prilocaine 2.5% Cream, (2) Lamotrigine 200mg Tablets, and (3) Meloxicam 15mg Tablets are being compounded together in a proprietary patent-pending process that results in the concentrations listed above in #6 which is CMPD Lidocaine 2%, Prilocaine 2%, Lamotrigine 2.5%, Meloxicam 0.09% Topical Cream. LAM* stands for Lipoderm Active-Max™ which is a trademark of PCCA. Spira-Wash-Gel™ is a water-miscible base and also a trademark of PCCA. Lidocaine 2% listed above equals Lidocaine HCl 2.46%. Prilocaine 2% listed above equals Prilocaine HCl 2.39%. Flurbiprofen, Nabumetone, and Gabapentin percentages listed above are based upon USP versions of the drug. Amitriptyline, Cyclobenzaprine, and Ketamine percentages listed above are based upon HCl versions of the drug. Magnesium percentage listed above is based upon a Sulfate version of the drug. As always, the FDA does not review any compounded medication for safety or efficacy.

EXHIBIT 2

Heritage COMPOUNDING PHARMACY

t: 1.877.703.0004
f: 1.877.871.7142
heritagecompound.com

COMPOUNDED TREATMENTS – TOPICAL PAIN MANAGEMENT

Patient's Name: [redacted] Date: 3/19/14

Patient's Date of Birth: [redacted] Patient's Phone Number:

Patient's Address: State: Zip:

Allergies: Last Four of SSN:

PLEASE FAX COPIES OF BOTH MEDICAL AND PRESCRIPTION CARDS

Physician's Name: Nanda Kumar Signature: V/O per Alyssa 3/19/14 415pm gr

Phone Number:

I have indicated by number(s) below, in order of preference, the medication(s) I am prescribing. The pharmacy shall dispense my first preference, unless not covered by the patient's insurance, in which case the pharmacy shall proceed in similar manner based on my order of preference. The pharmacy may dispense any drug selected below, regardless of order of preference, based on the patient's choice.

Prescribed Medications: *(CMPD indicates a medication that has been compounded by the pharmacy)*

1. ___ CMPD Flurbiprofen 10%, Cyclobenzaprine 1%, Gabapentin 6%, Lidocaine 2%, Prilocaine 2% in LAM*
2. ___ CMPD Flurbiprofen 10%, Amitriptyline 1%, Gabapentin 6%, Lidocaine 2%, Prilocaine 2% in LAM*
3. ✓ CMPD Nabumetone 15%, Amitriptyline 2%, Gabapentin 6%, Lidocaine 2%, Prilocaine 2%, Ketamine 5%, Magnesium 5% in LAM*
4. ___ Other:
5. ___ CMPD Lidocaine 2%, Prilocaine 2%, Lamotrigine 2.5%, Meloxicam 0.09% Topical Cream

Directions: *(Directions selected below apply to all medications indicated above – PLEASE CHECK DESIRED DOSING)*

1. ___ Apply up to four grams three to four times daily for treatment of pain and / or muscle spasms
2. ✓ High Dosing Regimen - Apply sufficient quantity to painful areas up to five times daily – maximum usage per day (in quantity) is 30 grams (6 grams per treatment)
3. ___ Other:

If checked below, please dispense the following as an accompanying prescription to the above prescribed therapy

1. ___ CMPD Nifedipine/Pentoxifylline/Ketamine/Gabapentin/Lidocaine/Prilocaine 10%/5%/10%/6%/3%/3%. Apply up to 4 grams three times a day, apply heat before and after. Wipe off excess.

Quantity to Dispense: 90 days *(30 day supply unless otherwise indicated here)*

Refills: *(Refills expire after one year if not utilized)*

(0) 1 2 3 4 5 1 Year

Three commercially available medications (1) Lidocaine2.5%/Prilocaine 2.5% Cream, (2) Lamotrigine 200mg Tablets, and (3) Meloxicam 15mg Tablets are being compounded together in a proprietary patent-pending process that results in the concentrations listed above in #6 which is CMPD Lidocaine 2%, Prilocaine 2%, Lamotrigine 2.5%, Meloxicam 0.09% Topical Cream. LAM* stands for Lipoderm Active-Max™ which is a trademark of PCCA. Spira-Wash-Gel™ is a water-miscible base and also a trademark of PCCA. Lidocaine 2% listed above equals Lidocaine HCl 2.46%. Prilocaine 2% listed above equals Prilocaine HCl 2.33%. Flurbiprofen, Nabumetone, and Gabapentin percentages listed above are based upon USP versions of the drug. Amitriptyline, Cyclobenzaprine, and Ketamine percentages listed above are based upon HCl versions of the drug. Magnesium percentage listed above is based upon a Sulfate version of the drug. As always, the FDA does not review any compounded medication for safety or efficacy.

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Heritage COMPOUNDING PHARMACY

t: 1.877.703.0004
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heritagecompound.com

COMPOUNDED TREATMENTS FOR TOPICAL PAIN MANAGEMENT

Patient's Name: [redacted] Date: 1-24-14

Patient's Date of Birth: [redacted] Patient's Phone Number: [redacted]

Patient's Address: [redacted] State: [redacted] Zip: [redacted]

Allergies: [redacted] Last Four of SSN: [redacted]

PLEASE FAX COPIES OF BOTH MEDICAL AND PRESCRIPTION CARDS

Physician's Name: Dr Nanda Kumar Signature: [signature]

Phone Number: [redacted] - Alicia

I have indicated by number(s) below, in order of preference, the medication(s) I am prescribing. The pharmacy shall dispense my first preference, unless not covered by the patient's insurance, in which case the pharmacy shall proceed in similar manner based on my order of preference. The pharmacy may dispense any drug selected below, regardless of order of preference, based on the patient's choice.

Prescribed Medications: *(CMPD indicates a medication that has been compounded by the pharmacy)*

1. ___ CMPD Flurbiprofen 10%, Cyclobenzaprine 1%, Gabapentin 6%, Lidocaine 2%, Prilocaine 2% in LAM*
2. ___ CMPD Flurbiprofen 10%, Amitriptyline 1%, Gabapentin 6%, Lidocaine 2%, Prilocaine 2% in LAM*
3. ___ Circulation: Nifedipine/Pentoxifylline/Ketamine/Gabapentin/Lidocaine/Prilocaine 10%/5%/10%/6%/3%/3%. Apply up to 4 grams three times a day, apply heat before and after. Wipe off excess.
4. (3) CMPD Gabapentin 10%, Lidocaine 2%, Prilocaine 2% in LAM*
5. (2) CMPD Nabumetone 15%, Amitriptyline 2%, Gabapentin 6%, Lidocaine 2%, Prilocaine 2%, Ketamine 5%, Magnesium 5% in LAM*
6. ___ Other: _____
7. (1) CMPD Lidocaine 2%, Prilocaine 2%, Lamotrigine 2.5%, Meloxicam 0.09% Topical Cream

Directions:
Apply up to four grams three to four times daily for treatment of pain and / or muscle spasms

Quantity to Dispense: 30 **days** *(30 day supply unless otherwise indicated here)*

If checked below, please dispense the following as an accompanying prescription to the above prescribed therapy

Refills: *(Refills expire after one year if not utilized)*

0 1 2 3 4 (5) 1 Year

Three commercially available medications (1) Lidocaine2.5%/Prilocaine 2.5% Cream, (2) Lamotrigine 200mg Tablets, and (3) Meloxicam 15mg Tablets are being compounded together in a proprietary patent-pending process that results in the concentrations listed above in #5 which is CMPD Lidocaine 2%, Prilocaine 2%, Lamotrigine 2.5%, Meloxicam 0.09% Topical Cream. LAM* stands for Lipoderm Active-Max™ which is a trademark of PCCA. Spira-Wash-Gel™ is a water-miscible base and also a trademark of PCCA. Lidocaine 2% listed above equals Lidocaine HCl 2.46%. Prilocaine 2% listed above equals Prilocaine HCl 2.33%. Flurbiprofen, Nabumetone, and Gabapentin percentages listed above are based upon USP versions of the drug. Amitriptyline, Cyclobenzaprine, and Ketamine percentages listed above are based upon HCl versions of the drug. Magnesium percentage listed above is based upon a Sulfate version of the drug. As always, the FDA does not review any compounded medication for safety or efficacy.

EXHIBIT 3

Heritage COMPOUNDING PHARMACY

t: 1.877.703.0004
f: 1.877.871.7142
heritagecompound.com

COMPOUNDED TREATMENTS – TOPICAL PAIN MANAGEMENT

Patient's Name: [redacted] Date: 3/19/14

Patient's Date of Birth: [redacted] Patient's Phone Number:

Patient's Address: State: Zip:

Allergies: Last Four of SSN:

PLEASE FAX COPIES OF BOTH MEDICAL AND PRESCRIPTION CARDS

Physician's Name: Nanda Kumar Signature: v/o per Alyssa 3/19/14 5:26pm gn

Phone Number:

I have indicated by number(s) below, in order of preference, the medication(s) I am prescribing. The pharmacy shall dispense my first preference, unless not covered by the patient's insurance, in which case the pharmacy shall proceed in similar manner based on my order of preference. The pharmacy may dispense any drug selected below, regardless of order of preference, based on the patient's choice.

Prescribed Medications: *(CMPD indicates a medication that has been compounded by the pharmacy)*

1. ___ CMPD Flurbiprofen 10%, Cyclobenzaprine 1%, Gabapentin 6%, Lidocaine 2%, Prilocaine 2% in LAM*
2. ___ CMPD Flurbiprofen 10%, Amitriptyline 1%, Gabapentin 6%, Lidocaine 2%, Prilocaine 2% in LAM*
3. ✓ CMPD Nabumetone 15%, Amitriptyline 2%, Gabapentin 6%, Lidocaine 2%, Prilocaine 2%, Ketamine 5%, Magnesium 5% in LAM*
4. ___ Other:
5. ___ CMPD Lidocaine 2%, Prilocaine 2%, Lamotrigine 2.5%, Meloxicam 0.09% Topical Cream

Directions: *(Directions selected below apply to all medications indicated above – PLEASE CHECK DESIRED DOSING)*

1. ___ Apply up to four grams three to four times daily for treatment of pain and / or muscle spasms
2. ✓ High Dosing Regimen - Apply sufficient quantity to painful areas up to five times daily – maximum usage per day (in quantity) is 30 grams (6 grams per treatment)
3. ___ Other:

If checked below, please dispense the following as an accompanying prescription to the above prescribed therapy

1. ___ CMPD Nifedipine/Pentoxifylline/Ketamine/Gabapentin/Lidocaine/Prilocaine 10%/5%/10%/6%/3%/3%. Apply up to 4 grams three times a day, apply heat before and after. Wipe off excess.

Quantity to Dispense: 90 days *(30 day supply unless otherwise indicated here)*

Refills: *(Refills expire after one year if not utilized)*

(0) 1 2 3 4 5 1 Year

Three commercially available medications (1) Lidocaine2.5%/Prilocaine 2.5% Cream, (2) Lamotrigine 200mg Tablets, and (3) Meloxicam 15mg Tablets are being compounded together in a proprietary patent-pending process that results in the concentrations listed above in #6 which is CMPD Lidocaine 2%, Prilocaine 2%, Lamotrigine 2.5%, Meloxicam 0.09% Topical Cream. LAM* stands for Lipoderm Active-Max™ which is a trademark of PCCA. Spira-Wash-Gel™ is a water-miscible base and also a trademark of PCCA. Lidocaine 2% listed above equals Lidocaine HCl 2.46%. Prilocaine 2% listed above equals Prilocaine HCl 2.33%. Flurbiprofen, Nabumetone, and Gabapentin percentages listed above are based upon USP versions of the drug. Amitriptyline, Cyclobenzaprine, and Ketamine percentages listed above are based upon HCl versions of the drug. Magnesium percentage listed above is based upon a Sulfate version of the drug. As always, the FDA does not review any compounded medication for safety or efficacy.